

# LETTERS TO THE EDITOR

## RITA trial protocol

SIR,—The merits of a well controlled clinical trial for the assessment of a new treatment in clinical medicine are established. Statisticians and epidemiologists have increasingly laid down more stringent and exacting criteria for conducting these trials and this has led to more valid results and conclusions. Recently, however, there have been examples where the criteria necessary to fulfil the demands of the statistician have been such that the study population recruited no longer represents the intended population and consequently the relevant clinical questions have not been answered.

The randomised intervention treatment of angina (RITA) trial (1989;62:411-4) suffers from a major methodological error in that it imposes on one group of patients—the angioplasty population—a treatment strategy that is not generally practised by the physician performing the procedure. The surgical strategies for revascularisation and the strategies for angioplasty are quite different and it is these strategies that should be compared rather than the likelihood that angioplasty will achieve exactly what the surgeon would wish to achieve.

Coronary artery bypass surgery aims to revascularise all important vessels with lesions that are haemodynamically significant at the time of the procedure or that are thought likely to become so in the future. The strategy of angioplasty varies between operators, centres, and individual patients, but it aims to make the patient symptom free with a pattern of disease that has a good prognosis. Lesions that are not haemodynamically significant are frequently not dilated because of the possibility of inducing a significant restenosis. With angioplasty the operator can postpone treating these lesions and treat them only if they become haemodynamically significant. The surgeon, because of the "cost" of surgery to the patient, does not have this option and therefore has to revascularise all vessels with potentially significant lesions at the time of the initial procedure.

By forcing a treatment strategy on the physician performing the angioplasty that is not widely used and that favours the surgical arm of the trial, the result of the RITA trial, whatever the outcome, will have few implications for clinical practice. It is unfortunate that a large amount of effort and money is being spent on this trial that does not address the clinical problems relevant to coronary artery revascularisation and will not provide reliable information on which the future allocation of resources can be based.

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This letter was shown to Dr Henderson, who replies as follows:

SIR,—Several of the points raised by Dr Beatt were initially considered very carefully by the

Protocol Committee of the RITA trial and his letter does not state the position correctly. Extensive surgical experience has shown the benefits of complete revascularisation and it was felt likely that the extent of revascularisation would also be important in patients treated by percutaneous transluminal coronary angioplasty. The angioplasty philosophy that only some of the important lesions need be dilated is not universally accepted and attempts to achieve complete revascularisation account for the tremendous increase in multivessel dilations in the United States.

The RITA trial requires that the cardiologist and surgeon plan to achieve equivalent revascularisation. There is no commitment for the cardiologist to dilate subclinical lesions that would be grafted by the surgeon nor is there a commitment for the surgeon to leave subclinical stenoses ungrafted. For example the surgeon might decide to bypass two tight stenoses and an additional 50% stenosis in another vessel. The angioplasty requirement would be to dilate the two tight stenoses but not necessarily the 50% stenosis.

The question whether incomplete revascularisation by angioplasty can produce results that compare with complete revascularisation by coronary artery bypass grafting is being addressed by other trials, such as the Bypass Angioplasty Revascularisation Investigation (BARI) and the Coronary Artery Bypass Revascularisation Investigation (CABRI), and it has always been recognised that these trials favour the surgical arm.

It seems that Dr Beatt has misunderstood that subclinical lesions need not be dilated in the RITA trial and this results in his final comments.

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For the RITA Trial Executive Committee

## Major complications of coronary arteriography: the place of cardiac surgery

SIR,—Stewart *et al* (1990;63:74-7) suggest that it may be more desirable to expand facilities at regional centres rather than devolve the investigation to district general hospitals, even though suitably trained cardiologists may practice there. Their study does not support this contention at all. It would be of interest to hear from the many hospitals already performing coronary angiography without cardiac surgery on site. Are these to be phased out because they are unsafe?

Indeed, several centres are performing not only coronary angiography but coronary angioplasty without on site facilities for cardiac surgery. Richardson *et al* recently reported the Belfast experience for percutaneous transluminal coronary angioplasty without on site facilities for cardiac surgery and concluded "With careful selection of patients coronary angioplasty may be safely performed in a hospital without on site cardiac surgery facilities, provided that these are available at a nearby centre."<sup>1</sup>

We are in an era of trying to improve the availability of cardiac investigations to increased numbers of the population but this demand cannot be met solely by the regional centres. To avoid unnecessary delay it seems reasonable for properly trained cardiologists to perform coronary angiography locally at district general hospitals provided the images

obtained are of diagnostic quality. In my opinion this proviso is the limiting factor. A study is currently under way at Maidstone and Guy's Hospital and preliminary results suggest that coronary angiography at district general hospitals is safe, reliable, feasible, affordable, and diagnostic.

The debate will clearly continue as Mills suggested in his editorial in the *British Heart Journal*.<sup>2</sup> The outcome may revolutionise the practice of cardiology in the United Kingdom.

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1 Richardson SG, Morton P, Murthah JG, O'Keeffe DB, Murphy P, Scott ME. Management of acute coronary occlusion during percutaneous transluminal coronary angioplasty: experience of complications in a hospital without on site facilities for cardiac surgery. *Br Med J* 1990;300:355-8.

2 Mills P. Should coronary angiography be performed in district hospitals?. *Br Heart J* 1990;63:73.

## Catheters or isotopes in the district general hospital?

SIR,—Stewart *et al* highlighted the potential problems of "routine" coronary arteriography performed without surgical cover (1990;63:74-7), and Mills has used their findings to fuel the debate about the safety of coronary arteriography in the district general hospital (1990;63:73). I believe that the debate is academic.

In patients with stable coronary artery disease diagnostic and therapeutic decisions can usually be made on the basis of the history, examination, electrocardiography, and non-invasive assessment of myocardial perfusion by thallium-201 or one of the newer technetium isonitriles.<sup>1</sup> But cardiologists who are unaware of the high quality of modern emission tomography feel the need to resort to coronary arteriography to be on safe ground. Non-invasive tests alone, however, can be used to decide who is at high risk of future cardiac events and could presumably benefit from intervention and who may continue on medical treatment.<sup>2,3</sup> Indeed, myocardial perfusion imaging is better than coronary arteriography for predicting outcome.<sup>4</sup> A knowledge of the coronary anatomy (as opposed to function) is needed only to guide the interventional cardiologist or the cardiac surgeon and therefore should be limited to the specialist centre. Here the decision to intervene has usually been made before referral and coronary arteriography cannot be avoided; but myocardial perfusion imaging remains important as an objective indicator of the site, extent, and depth of ischaemia.

Good quality nuclear cardiology is available only in a few district hospitals because many see it as a specialist technique that should be practised only in a specialist centre. The opposite is the case and the technique is most effective in aiding triage in hospitals without access to coronary arteriography.<sup>5</sup> Most districts do have access to nuclear medicine equipment but a recent survey showed considerable underuse of nuclear cardiology in the United Kingdom.<sup>6</sup> Only inertia and poor training in nuclear techniques can explain this.

Some cardiologists dismiss these views as those of an enthusiast. It is true that enthusiasm is an important part of providing a reliable nuclear cardiology service, but those